

Amendments to the claims

1 (previously amended): An active-containing dissolvable film prepared by solubilizing or dispersing an active ingredient in an aqueous environment, forming a mixture comprising the active ingredient and film-forming ingredients, coating the mixture onto a substrate material to form a film, and then drying the film to a moisture content of less than about 15 weight % moisture, said active ingredient having a water solubility of less than about 1 g/4mL at room temperature and being present in the film in amounts sufficient to impart a desired action upon administration of a single dosage form of the active-containing dissolvable film.

2 (previously amended): The film of claim 1 wherein the active ingredient has a water solubility of less than about 1 g/10mL at room temperature.

3 (original): The film of claim 1 wherein the mixture is in the form of a solution.

4 (original): The film of claim 3 wherein a solution is formed upon the application of heat and/or agitation of the mixture.

5 (original): The film of claim 1 wherein the mixture is in the form a suspension.

6 (original): The film of claim 3 wherein said active ingredient is caffeine.

7 (original): The film of claim 6 comprising at least about 18 % by dry weight of caffeine based on the weight of the final formulated film.

8 (original): The film of claim 7 comprising at least about 20 % by dry weight of caffeine.

9 (original): The film of claim 8 comprising at least about 25 % by dry weight of caffeine.

10 (original): The film of claim 1 wherein said film-forming ingredients comprise a starch component comprising at least about 85 % modified starch.

11 (original): The film of claim 10 wherein the starch is selected from the group consisting of a hydroxyalkylated starch and a succinated starch.

12 (previously amended) A method of making an active-containing dissolvable film comprising an active ingredient, the method comprising solubilizing or dispersing an active ingredient in an aqueous environment, forming a mixture of the dispersed or solubilized active ingredient and film-forming ingredients, coating the mixture onto a substrate material to form a film, and then drying the film to a moisture content of less than about 15 weight % moisture, said active ingredient having a water solubility of less than about 1g/4mL at room temperature and used in amounts sufficient to impart a desired action upon administration of a single dosage form of the active-containing dissolvable film.

13 (original): The method of claim 12 wherein the mixture is in the form of a solution or in the form of a suspension.

14 (original): A dissolvable caffeine-containing film comprising at least about 18 % by dry weight of caffeine based on the weight of said film.

15 (original): A single dosage dissolvable film of claim 14 comprising from about 20 mg to about 30 mg of caffeine per single dosage film.

16 (original): A method of administering an active ingredient to an individual needing or desiring said active ingredient, said method comprising applying the active-containing dissolvable film of claim 1 to a moist area of an individual, upon which application the active is released.

17 (original): The method of claim 16, wherein the film is applied to the tongue.

18 (original): The method of claim 16, wherein the film is applied to traumatized tissue.

19 (original): The method of claim 18 wherein the traumatized tissue is skin.

20 (original): The method of claim 17 wherein the active ingredient is caffeine.